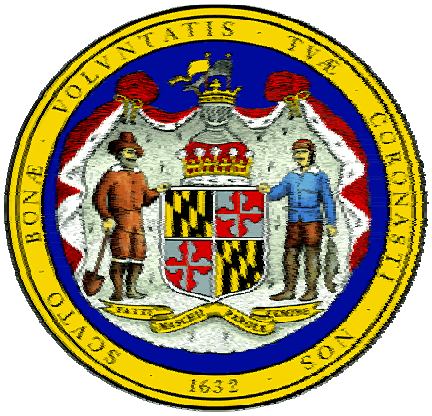
COMAR 10.24.17

State Health Plan: Specialized Health Care Services- Cardiac Surgery and Therapeutic Catheterization Services

Summary of Written Public Comments



MARYLAND HEALTH CARE COMMISSION
Division of Health Resources
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April 19, 2001

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Summary of Written Public Comments Received on
COMAR 10.24.17 STATE HEATLH PLAN: SPECIALIZED HEALTH CARE SERVICES- CARDIAC SURGERY AND THERAPEUTIC CATHETERIZATION SERVICES

A. Need Projection Policies

Definition of Planning Regions

•**Martin L. Doordan, President of Anne Arundel Medical Center (AAMC),** indicated that AAMC does not agree with the plan. He believes that the plan's central theme—that the State's major community hospitals outside of Washington and Baltimore have no role other than to feed the existing providers under the banner of regional health care—is an obstacle to the delivery of cardiac care. The result is that Anne Arundel County cardiac patients will be forced to leave the county for care, and AAMC will be forbidden from providing the standard of care for the many heart attack and heart disease patients we serve. AAMC disagrees strongly with the regional concept embodied in this plan. The State's largest and most sophisticated community medical centers should be able to treat the patients who rely upon them for care in a timely and appropriate manner, and under this plan we simply cannot.

•**Wynee E. Hawk, Vice President for Government Relations at GBMC**, commented that the Commission reached the wrong conclusion because it is wedded to the concept of "regionalization" of open heart services and the belief that the public is better served by limited access to care by having a very limited number of very high volume providers. GBMC strongly disagrees. The state's largest and most sophisticated community medical centers should be able to treat the heart disease patients who rely upon them for care….Need should be measured in terms of whether the individual hospital could demonstrate that it could meet the quality standard, by evidence as simple as that it historically treated sufficient patients that were forced to transfer elsewhere for their care.

•**Raymond A. Grahe, Vice President for Finance at Washington County Hospital**, indicated that a more accurate representation would be the combination of Frederick and Washington Counties in a separate region. This would more accurately reflect patient migration for a service such as OHS. Mountains geographically separate Allegany and Garrett Counties. Residents of Washington and Frederick counties will not travel west but also are not part of the D.C. metropolitan area. Washington County Health System has a presence in Western Frederick County with a primary care practice in Myersville, Maryland, which results in Washington County Hospital receiving 3% of its inpatient admissions from Frederick County. (John H. Hornbaker, Jr., M.D., Gary Papuchis, M.D., Jeffrey D. Jones, M.D., Zubair H. Faridi, M.D., Scott M. Hamilton, M.D., and W. Stephen Hood, M.D. wrote to endorse and support comments from the Washington County Hospital.)

Use Rate Assumptions in Projecting Future Cases

•**Keith M. Lindgren, M.D.**, a member of the Technical Advisory Committee commented that use rates for cardiac surgery are not growing. They are currently flat and forecasts actually project a decline in the absolute number of open heart cases primarily because of the success of less invasive therapies (e.g., medications). Considering current conditions, if another program is introduced in lower Montgomery County, Washington Adventist Hospital and Prince George's Hospital Center will be impacted. Among other things, current labor shortages will be amplified and health care costs will rise.

•**Beverly Harvey, Assistant Vice President for Citibank**, wrote in opposition to the proposed plan. Use rates are declining for cardiac surgery due in large measure to advances in less invasive procedures and drug therapies. Given this trend and the fact that capacity exists with current Maryland providers, it does not make sense to introduce additional capacity into the system for a specialized service. Formulating a plan based largely on market share calculations seems ill-advised, especially given that clinical outcomes are outstanding among current Maryland providers and that there are no wait times for cardiac surgery anywhere in the State.

•**Peninsula Regional Medical Center** addressed the overall concept of need for additional open heart programs. Current need across the State for open-heart surgery services has remained stagnant, and it is expected that an increasing percentage of heart patients will be treated non-surgically in the future with less costly and less invasive measures. There are no wait times for patients who need this service and with the addition of the new program in Cumberland, every heart patient in Maryland is assured geographic access to care. Recent figures document that open heart surgery use rates have begun to decline or stabilize among Maryland residents, lending further support that adequate capacity (if not excess capacity) exists in Maryland…Forecasts and clinical practice trends argue for a very conservative approach towards increasing operating room capacity and open heart surgery programs. Cardiovascular disease can be treated medically, surgically or via transcatheter techniques and important changes are occurring in clinical practice that are likely to impact the caseload in each of these areas…*"As a result of the success of PTCA anti—restenosis techniques, the number of open heart surgeries in the U.S. is forecasted to decline from approximately 430,000 in 1998 to an estimated 375,000 in the year 2003.*"

Measurement of Program Capacity

•**William G. Robertson, President and CEO of Adventist HealthCare**, indicated that the proposed regulations ignore the counsel of the Technical Advisory Committee. The TAC recognized that the measure of operating room capacity did not explicitly measure the balance of

the hospital's infrastructure when it assigned to each OHS program the capacity to perform 500 OHS cases per dedicated OR per year. For that reason, the TAC counseled that the existing capacity measure be expanded to include the other resources needed to care for the OHS patients, including staff availability, in the existing programs. The TAC did not recommend that operating rooms be abandoned as a measure of capacity; it recommended that the measure be refined to consider other factors…We strongly urge that the proposed regulations not be adopted in final form; that the TAC recommendations on OHS capacity and elective angioplasty be adopted in their entirely; and that the utilization, manpower, and treatment capacity of existing OHS programs be objectively measured consistent with the TAC's recommendations in determining whether or not a new OHS program is needed.

•**Keith M. Lindgren, M.D.**, a member of the Technical Advisory Committee, indicated that Recommendation 6.2 in the TAC Report recommended that the measurement of available system capacity be re-defined to incorporate other factors, such as monitoring of patient outcomes, assessment of future need, staff availability, access, and cost in determining the need for additional OHS programs in Maryland. In the report, "other factors" implied that the number of operating rooms was one of many factors that should be considered. These factors have not been identified and studied. A multi-factorial capacity measure is indeed possible to develop and should be constructed. From there, a thorough survey should be conducted and need determined before approval of any proposed recommendations.

•**T. Wayne Hobbs, Assistant City Administrator for the City of Takoma Park**, Maryland, wrote on behalf of the City in opposition to the cardiac surgery regulations as they are proposed. Specifically, we are concerned about the impact these regulations will have upon Washington Adventist Hospital, which has been a stellar provider of cardiac services in our region for more than 30 years….The prospect of placing another regional cardiac surgery center so close to Washington Adventist Hospital does not seem to be an appropriate use of health care resources. And, given the controversy surrounding the capacity measure established by the Commission, we urge you to withdraw these regulations as currently proposed.

•**Halsey William Heslop**, a retired United Methodist minister, wrote in opposition to the proposed regulations….He found it extremely curious that the Commission is changing the way capacity is being measured. It makes no sense to me to go against the recommendations of cardiologists and cardiac surgeons. As a minister, I have known hundreds of people who have had cardiac surgery. All of them, including myself, received surgery when we needed it and I do not know of one person who did not receive excellent care. As someone who has been in and visited hospitals for more than 40 years, I do not believe there is any problem with the current system of care in our region….It does not make sense to me to change a system of care that has proven to be so effective.

•**Ralph S. Tyler, Esq., on behalf of MedStar Health**, noted that the proposed new methodology provides that the capacity of any program cannot be greater than the higher of 800 cases or 50 percent of the projected gross need for the planning region. There is literally no rational basis for this proposed change and even those urging its adoption do not claim to the contrary. Rather, what happened here is that a decision was made (for reasons that are not apparent and which have yet to be articulated) that there "should be" another cardiac surgery

program in the Washington Region and the need methodology then had to be skewed because, in fact, there is no need for another program in that region. Stated differently, because there is no factual basis for concluding that there is a need for additional cardiac surgery services in the Washington Region, a methodology was constructed that deliberately disregards the facts. This is neither sound health planning nor, we respectfully submit, lawful….there are existing cardiac surgery programs in Maryland within the Washington Region performing fewer procedures than the research establishes is necessary to obtain the best results for patients. Manipulating the methodology to find a "need" for another program will further decrease the number of procedures performed in these existing Maryland programs. This has to be true because the evidence is—and there is no dispute on this point—that the demand for these services is essentially flat…MedStar urges the Commission to reject the proposed amendment to the State Health Plan that would change the methodology for calculating the need for cardiac surgery facilities.

•**Kevin J. Sexton, CEO of Holy Cross Hospital**, supported allowing Maryland hospitals in the Washington metropolitan area that do not currently perform OHS to apply for a CON and for the Commission to award a CON if an applicant convinces the Commission that granting that program a CON would be in the public interest. This change in policy that the Commission has adopted in COMAR 10.24.17 changes the definition of capacity in the State Health Plan. Holy Cross Hospital strongly supports the Commission's proposed definition of capacity and, in particular, the idea of considering market share or market concentration in determining whether additional competition might be in the public interest. Sexton cited research studies indicating that it is very reasonable to expect lower prices to be associated with significant decreases in concentration.

•**Peninsula Regional Medical Center** expressed concern on the issue of capacity as found on pages 62 and 63 of the proposed regulations. Specifically, the comments and methodology employed by the Commission presents a false and inaccurate assessment of the capacity of open heart surgery programs in Maryland. Again, the Commission chose to ignore the recommendation of the TAC that suggested measures of capacity to include such factors as the number of operating rooms, wait times, staffing, transport, and patient outcomes. The TAC report documented that existing open heart providers demonstrate more than adequate capacity as measured by available operating rooms…Another important measure of specialized cardiac capacity is the number of intensive care beds. Occupancy rates in these units similarly demonstrate that adequate capacity exists among existing open heart providers.

•**Stephen J. Sfekas, on behalf of Dimensions Healthcare System**, urged the Commission to withdraw the proposed section and to reconvene the TAC to review the capacity measure in the plan. Despite thorough review of most of the plan's provisions over the last six months, the current version of the capacity measure has received minimal scrutiny either as to clinical issues or as to economic or financial impact. …the capacity measure, one of the core elements of the new plan, has avoided the type of sustained and detailed analysis that other portions of the plan such as the volume standards have received. As of this moment in particular, there has been no expert analysis of cardiac surgery capacity to determine whether or not there is any merit from a clinical, financial or economic perspective to the type of market share approach in the proposed plan section. Furthermore, there has been no analysis performed

as to whether or not the three central premises of the market share approach, i.e., that the Washington market is excessively concentrated, that this concentration is bad and that creating one more program would have a favorable impact on the alleged problem are valid. The arguments in favor of the market share approach do not hold up even under cursory examination. The alleged excessive concentration of volume is largely an artifact of the plan's approach of ignoring Northern Virginia hospitals and populations. …a comparison of Baltimore and Washington programs indicates that the Washington area is only somewhat more concentrated than Baltimore…In short, there is less difference between the two marketplaces than meet the eye and the plan section appears to be aimed at a non-existent target…Even if there were excessive concentration in the Washington area, there is no reason to believe that approving an additional program would solve the problem. The Washington area is subject to three different approval processes for new programs. Since 1990, three programs have been approved, none of which has achieved 200 procedures in 1999. Three of the six programs were in university-based hospitals. Washington is an area with ample consumer choice and access. It is not clear why the addition of one more suburban community hospital program to this mix would change the characteristics of this market. Conversely, there is reason to believe that several of the Washington area hospitals may be able to increase volumes on their own….Finally, even if we were to assume that the Washington Metropolitan area is too highly concentrated, it is not clear that there are any ill effects from the Commission's perspective. The Commission's mission is to ensure quality, access and cost containment in the health care system. There has been no showing in this proceeding that the allocation of cases in this region has caused a decline in the quality of the service, or access to the service or an increased cost of the service…The Commission should not adopt this plan section without making a thorough analysis of the clinical and economic impact of the new capacity measure.

•**Jack C. Tranter, Esq., on behalf of Suburban Hospital,** indicated that Suburban believes that the 1999 TAC got it right when it included Recommendation 6.1 in its Final Report to the Commission: *The TAC recommends that the capacity benchmark used in the 1997 State Health Plan chapter on OHS (two cases per operating room per day) be eliminated.* As the proposed regulations recognize, the 500-case per OR benchmark produces such large, unrealistic case excesses that no new program will ever be approved in Maryland. Bluntly stated, the 500-case per OR capacity measure imposes a moratorium and protects the Hospital Center with its almost 75 percent market share from any new competition for all time. ..The proposed regulations return to the approach followed in the 1985 and 1990 OHS sections by using historical utilization to measure system capacity. Specifically, the proposed regulations measure system capacity based on the highest volume achieved by each provider in the last three years. In addition, a 50% cap is assigned to the capacity of each program. Use of a "cap" recognizes the dysfunctional nature of the Washington cardiac surgery market and allows the Commission to consider proposals to develop a new program in that area. ..Adoption of the need methodology found in the proposed regulations would: (1) remedy the limited choice available in the D.C. market; (2) improve access for Maryland residents; (3) increase price competition; and (4) generate significant savings for the Medicare program and, most likely, other payers.

•**Paul Corso, M.D., Director of the Cardiac Surgery Section of the Department of Surgery at Washington Hospital Center**, wrote in opposition to the proposed regulations…...He indicated that capacity is incorrectly defined in the formula that determines

need. True capacity is a measure of what one is capable of doing. He concern was that planners have removed a proven, efficient capacity threshold of 500 cases/OR/year and instead accepted current volume performance as the measure of an institution's capacity—that is, with the exception of one program that did achieve efficient levels. The proposed regulations create false need for additional programs. Existing facilities have more than adequate capacity, and easily accommodate patients' need for geographic access to open heart surgery and PTCA services. By incorporating inefficient capacity standards, the State would be endorsing and subsidizing under-utilized cardiac surgery programs.

Patient Migration Patterns

•**Peter P. Parvis, Esq., on behalf of Frederick Memorial Hospital,** commented that patient migration is driven by factors not measured in the proposed chapter on specialized cardiac services—the fact that Western Maryland patients are required to go outside the region for care, and the ability of insurers to force patients into high volume centers even for routine heart care. Patient migration similar to that for other medical surgical services would be likely to occur if the CON constraint were removed, and should be used in areas without an OHS provider in the county if the need projections will be applied to PTCA as well as OHS. The Commission should consider the needs of Frederick County on their own merits. The proposed plan chapter does not do that. Table 7 reveals that 271 Frederick County residents received OHS in 1999, more than twice as many as were reported for Allegany County. Frederick County has a greater rate of growth than Allegany County, and expects that the growth and aging of its population will result in increasing need in Frederick County…Frederick Memorial Hospital objects strongly to the policies in the need calculation that ignore actual need in Frederick County by virtue of a perceived "optimal migration", coupled with an artificial and unsupported retention policy that suggests that Frederick County residents are served by a facility in Cumberland.

•**Raymond A. Grahe, Vice President for Finance at Washington County Hospital**, wrote that the methodology utilized by the Commission does not adequately address the need for Western Maryland. Utilization of a 45% retention rate significantly reduces the projected number of cases for 2002 and beyond. This low retention rate fails to adequately address access issues for the residents of Western Maryland. The Commission states in several different places the need to address access and the hardship of travel for the residents of Western Maryland but fails to do so in its calculations. We believe that the Commission should increase potential retention to be adequate to retention of other inpatients services in Western Maryland….Additionally, the Commission does not project in-migration of cases into Western Maryland because there has been no history of in-migration, which is due to the previous lack of an open heart program. (John H. Hornbaker, Jr., M.D., Gary Papuchis, M.D., Jeffrey D. Jones, M.D., Zubair H. Faridi, M.D., Scott M. Hamilton, M.D., and W. Stephen Hood, M.D. wrote to endorse and support comments from the Washington County Hospital.)

Other Issues

Washington vs. Baltimore Cardiac Services Market

•**William G. Robertson, President and CEO of Adventist HealthCare**, stated that there is no market dysfunction in the Washington Metropolitan Region. In fact, the Washington Regional market is functioning quite well, responding appropriately to regulatory and market forces with respect to utilization, program, costs, referral patterns, accessibility and other indicia of a properly functioning market in a regulated environment. The HSCRC regulated costs of providing OHS and interventional cardiology services in the Maryland hospitals located in the Washington Region, including Washington Adventist Hospital, are less than the costs reported elsewhere in the State. The proposed regulations introduce into the SHP a new concept, seeking to define a "dysfunctional market" for a health care service and then intervening into that market to address the perceived "dysfunction". In essence, while there may be an ample number of freely competing OHS programs in a region, each of which has unused capacity, a region is defined in the proposed regulations as dysfunctional when a significant number of patients, referring physicians, and payers seek services at one specific high-quality OHS program and not at others. A new OHS program should not become "needed" and eligible for CON approval simply because one high-volume OHS program in the Washington Region has become too successful in delivering OHS services with excellent outcomes, the latest techniques and technologies and good nursing care, and when those OHS services were delivered at prices acceptable to patients and payers. The proposed regulations seek to "correct" this alleged failure or "dysfunction" by the new methodology that allocates future OHS cases away from that program, and reserves that "need" exclusively for a new OHS program in Maryland….Another Maryland OHS program will have a negative impact upon current Maryland providers. Currently there are six-non-federal OHS programs in the Washington region. Four of these are below 200 cases. At the same time, Georgetown University Hospital's incorporation into the Medstar system may well cause its volumes to increase. Recent developments at GWU Medical Center may well lead to increases in volumes at that institution. Prince George's Hospital Center has also pointed out that it has secured a contract with a major payer in the Washington Region, reflecting and helping to ensure its continued success…It should also be pointed out that the new OHS program in Western Maryland is being implemented. Residents of that affected area are expected to remain in Western Maryland, yet they are not prohibited from receiving care in the Washington and Baltimore Regions. Ignoring actual capacity, using the OHS chapter's methodology and the TAC recommendations, leads to finding a need for a new OHS program in the Washington Region when none exists. The proposed regulations threaten the Western Maryland OHS program by creating a situation where Washington Region hospitals will seek to retain those Western Maryland cases since their true capacity and volumes will be ignored. Adding another OHS program in the Washington Region while the new OHS program in Western Maryland is just getting off the ground is a formula for market disruption, not improved market functioning. Approval of a new OHS program does not guarantee that the Commission's intent to reduce the volumes of certain high volume programs in the District of Columbia, and reallocate those cases to a new OHS program in Maryland, will be accomplished. Rather, it is far more likely that cases would be drawn from all existing programs, thereby not accomplishing the intended effect on non-Maryland providers, and resulting in the very undesirable effect of reducing volumes not only at Washington Adventist, but also at low volume providers such as

Prince George's Hospital Center, that are struggling to achieve program success, and would be further hampered in their attempt to achieve such success.

•**Warren A. Green, President and CEO of LifeBridge Health**, said that he was particularly pleased that the proposed revisions clearly acknowledge that Central Maryland has more than adequate cardiac surgical capacity, and that the initiation of additional programs in this region would serve only to dilute the quality of the excellent programs that currently exist. Even if the Commission feels compelled to reconsider the proposed need methodology because of its implications for the suburban Washington region, we urge the Commission not to make any changes that would potentially disturb its conclusion that there is no need or additional programs in Central Maryland. When an issue has sparked as much controversy as this one has, it is almost axiomatic that no interested party will be completely pleased with the final proposal, no matter how carefully crafted that proposal may be. There are, indeed, certain elements of the proposed regulations that continue to concern us…..Our raising of these issues, however, should not obscure our firm belief that the Commission's finding regarding the absence of need for additional programs in Central Maryland must be reflected, quickly, and definitively, in final regulations.

•**Jack C. Tranter, Esq., on behalf of Suburban Hospital**, indicated that a comparison of the Baltimore and Washington OHS markets demonstrates that the proposed regulations should be adopted so that the Commission may consider proposals to develop a new cardiac surgery program in the D.C. area. ….Unlike Baltimore with its five "right-sized" competitive programs, the D.C. market is dominated by a single large provider, the Washington Hospital Center. In 1999, the Hospital Center performed nearly three out of every four cardiac surgeries in the Washington region. Although, nominally, there are six OHS programs in the Washington region, in fact, there are just two….In 1999, four of the six existing providers experienced volumes that are well below the 200 case minimum volume standard set forth in the State Health Plan. The foregoing low volumes are even more remarkable because these four programs have been in existence for many, many years. Indeed, it is particularly telling that none of these programs is anywhere near the 350-case threshold volume level expected of a "mature" program, i.e., a program providing OHS services for three or more years. …Despite continuing low volumes experienced by these four programs, the 1997 State Health Plan assigned capacity of 3,000 cases to these programs because collectively they have six operating rooms. Yet, all 395 of the cardiac surgery cases performed at these programs in 1999 (the 1998 volume for GWU) could have been performed in a single operating room, under the State Health Plan's logic. The dysfunctional nature of the D.C. market is further demonstrated by the Hospital Center's increasing dominance. In 1994, the Hospital performed roughly 50 percent of all cardiac surgery in this area. However, the Hospital Center's already large market share has increased dramatically over the last five years, i.e., from 50 percent to 73 percent…this means that the Hospital Center now performs three out of every four cardiac surgeries in the D.C. area.

B. Quality of Care Policies

Minimum and Threshold Volume Standards: Open Heart Surgery

•**James C. Ballantine**, a cardiac patient and survivor for 20 years and resident of Annapolis, said that to have true excellence one must do something many times when dealing with complex issues—be that engineering or medical technology. Repetition is absolutely essential—and having a higher volume of work in a shipyard, or what is being considered here, having a higher patient volume in a medical facility, is absolutely essential to having a chance at being, or continuing to be, a "center of excellence". We are not dealing with new technologies, where added risks for progress sake may be justified. We are not in a clinical trial phase or development. We have a well-developed and essentially a mature medical technology, and it can only get better if we do not spread thin the volume of patients.

•**Wynee E. Hawk, Vice President for Government Relations at GBMC**, commented that the plan discusses the link between volumes and quality, with a conclusion that no existing program should fall below 350 cases, even with a minimum standard of only 200 cases and studies suggesting an even lower number. GBMC agrees that there is a connection between volumes and quality and concurs that 350 is an appropriate number. However, the link to quality does not support the rest of the conclusions in the plan, the conclusion that there should be no new programs in central Maryland….All of the central Maryland programs are far above the plan's threshold standards. The only reason the plan finds no need is because it measures capacity by the ability of the "haves" to continue to treat more and more patients, not because in fact there is no need, or because the existing programs would be harmed if access were increased.

Co-Location of Angioplasty and Open Heart Surgery Services

•**William G. Robertson, President and CEO of Adventist HealthCare**, noted that the proposed regulations would permit the approval of elective angioplasty at certain hospitals without on-site OHS backup. This extension was not recommended by the TAC and is contrary to the recommendations of the American College of Cardiology/American Heart Association. The Commission is currently looking closely at the C-PORT study, which is being shifted to become a registry. The close review of the treatment of C-PORT itself highlights why an expansion of this kind of exemption to elective angioplasty is not warranted. The procedure involved is an elective one, so that there is time for the patient to be treated in a program with OHS backup. Also, granting such an exemption would be contrary to efforts to ensure that angioplasty programs maintain adequate volumes of cases to maintain optimal proficiency.

•**Martin L. Doordan, President of Anne Arundel Medical Center (AAMC)**, noted that the plan recognizes the growing use and safety of angioplasty and stents, but still requires on-site open heart surgery backup for angioplasty. We do not disagree with the requirement, but

we disagree with the ultimate answer of continuing the status quo and forcing Anne Arundel County patients to travel to Baltimore or Washington for what is now basic heart care. The plan acknowledges growing evidence of the need for rapid and effective primary angioplasty for older MI patients. That time is golden and the patients who come to AAMC with a heart attack cannot be transported to one of the "haves" in a timely manner. Its one possible answer to this problem—one pilot program that may be approved for a short period of time—is not enough.

•**Keith M. Lindgren, M.D.**, a member of the Technical Advisory Committee, indicated that absolutely no medical professional association or society endorses the provision of elective angioplasty in the absence of co-location of cardiac surgery services. The TAC recommended continuation of the C-PORT project that is specific to primary angioplasty, and further recommended that policy issues on co-location be review on an on-going basis to reflect results of current research. The TAC did not recommend that Maryland hospitals participate in that research, nor should they.

•**Peter P. Parvis, Esq., on behalf of Frederick Memorial Hospital**, said that the Hospital does not believe that it needs to offer open heart surgery at this time. However, the proposed plan regulates far more than OHS. Frederick Memorial Hospitals offers vascular and thoracic surgery, as well as cardiac catheterization services. Frederick Memorial Hospital does not believe that the plan can or should regulate cardiac procedures that are not open heart surgery. Frederick recognizes that the standard of care at this time requires on-site open heart surgery in order to perform elective PTCA procedures and will honor that standard of care. However, Frederick Memorial Hospital expects that advances in medical care will be developed that would make coronary angioplasty more accessible at sole community providers such as Frederick and to the patients they serve. Frederick believes that the standard of care, and not a regulation of the Commission, should control that medical decision. Frederick believes that continuing advances in medical treatment may, perhaps quickly, change the standard of care to a point where some services that this plan chapter regulates both can and should be available at major sole community providers like Frederick. This plan would effectively prohibit offering any such services without regard to medical advances. The statute requires the Commission to regulate "open heart surgery" and Frederick believes the Commission should not extend its regulatory reach by defining open heart surgery to include either closed heart surgery or coronary angioplasty…..If primary coronary angioplasty can be safely offered at sole community hospitals without on-site open heart programs, the decision of whether to offer it should be left to the hospital and its medical staff. The current SHP makes that choice for all hospitals, and in so doing may decrease access to care that could help heart attack patients in Frederick County….Frederick Memorial Hospital believes that the Commission should focus on the role of sole community providers, and explore increased access to PTCA in sole community providers without on-site OHS….Frederick Memorial Hospital believes that sole community providers—particularly a provider such as Frederick with more than 16,000 annual admissions—should be permitted to offer PTCA as soon as possible.

•**Kevin J. Sexton, President and CEO of Holy Cross Hospital**, expressed strong support for Policies 5.1 and 5.2. These policies address the limited exemptions to the requirement that PTCA procedures be performed only in hospitals with on-site cardiac surgical backup. The C-PORT program (Policy 5.1) has been very positively received by our medical

staff and offered a tremendous health benefit to the patients who have undergone this procedure at Holy Cross Hospital…The success of the C-PORT program reinforces the value of Policy 5.2. Great advances are being made in non-surgical treatments for cardiac disease. Policy 5.2 which recommends that the Commission "consider a pilot project to assess whether it would be appropriate to modify current policy…for certain groups of elective angioplasty patients" is a prudent approach to ensuring that Maryland providers can incorporate advances in medical research and resultant changes in practice patterns. The C-PORT program has demonstrated that a rigorously designed research study can effectively assess the benefits and risks of new treatment modalities. Without Policy 5.2 there will be no opportunity for the Commission to even consider changes to its current requirement for on-site cardiac backup for elective angioplasty, and no opportunity for Maryland residents to benefit from advances in medical research related to cardiac care. I strongly urge you to retain Policy 5.1 and 5.2 as written in the proposed permanent regulations.

•**Warren A Green, President and CEO of Lifebridge Health**, expressed concern about the proposed research project to examine the performance of elective angioplasties at facilities that lack open heart capacity. We fully support the on-going C-PORT study, which allows the performance of primary angioplasty on cardiac patients who present at hospital emergency rooms in an acute condition. We do not understand, however, why it should even be appropriate to perform elective angioplasty outside of a hospital with open heart backup. While the percentage of angioplasties that require surgical intervention has certainly declined over the years, the occasional completion still arises, and in those cases the availability of open heart backup can mean the difference between life and death. Any study involving the performance of elective angioplasties without open heart backup will inevitably subject patients to unnecessary risks, and we do not believe that the Commission should facilitate, let alone encourage, such an effort.

•**Richard G. McAlee, Esq, on behalf of Southern Maryland Hospital Center**, indicated that there has been a disproportionate amount of controversy concerning Policy 5.2, which states that the Commission should "consider a pilot project to assess whether it would be appropriate to modify current policy" requiring on-site open heart surgical backup for "certain groups of elective angioplasty patients." Some parties have equated Policy 5.2 with doing away entirely with on-site open heart surgical backup for angioplasty. This is clearly not the case. The Commission has expressed a cautious, conservative intension to "consider" a limited "pilot project" which would have as its purpose the assessment of whether on-site backup is really necessary. This is several steps removed from any decision to modify the current policy. The controversy surrounding this policy is largely moot because the Commission currently has no legal authority to regulate angioplasty in any event. The authority to regulate changes in hospital services is clearly delimited in the Commission's enabling legislation….In other words, given the Commission's current enabling legislation, any hospital in Maryland is legally allowed to establish an angioplasty program without permission from the Commission. Whether it would be advisable to do so from a clinical perspective is another matter, but that decision is left to individual hospitals. This stands in sharp contrast to open heart surgery, which is specifically listed as an exception to the general rule that hospitals may "establish, increase, or decrease a health care service" without permission from the Commission.

•**Daniel L. Herr, MS, MD, FCCM, Chairman of the Institutional Review Board at MedStar Research Institute**, opposed the plan on the basis of inappropriate use of research as loopholes to medical practice guidelines established by professional societies. Specifically, he called into question (1) continuance of C-PORT under an unmonitored registry approach, and (2) recommendations for unethical research on human subjects in Maryland hospitals for patients requiring elective angioplasty. Regarding extending the exemption for a C-PORT registry, he said that the project was initiated as a full scientific study that was never completed and not fully supported economically or by referring physicians. At the time of its conclusion, it was (and still is), severely underpowered and not representative of MI patients requiring care in Maryland hospitals….While the intent of research made clinical and ethical sense, I raise the issue of a State planning body continuing an exemption based on one study that does not have definitive results. Moreover, the State is proposing to continue the exemption without apparent and adequate mechanisms to fully understand outcomes and results. Registries do not systematically investigate and compare treatment methods between those who do receive and do not receive a certain type of care. At best, registries are rudimentary monitoring tools that are only as good as the objectivity of those controlling data input and the quality of monitoring controls. Regarding the proposal to allow research studies on elective angioplasty, I have serious concerns regarding a breech of research ethics. These issues would be identified in the research review process. This process includes a review by a Research Committee, who evaluates the scientific merit, design and methods, as well as the full IRB who reviews on scientific design, ethical merit and assures that appropriate steps are taken to protect the rights and welfare of human subjects participating in the research. Research in elective angioplasty violates two fundamental criteria for human research. First, the study has to demonstrate sufficient evidence that the proposed method of treatment can provide a better or improved outcome for patients than the current standard of treatment. In the case of elective angioplasty, there are no data available that suggest outcomes for patients are better under conditions such as that found in low-volume community hospitals. In fact, numerous studies point to that patients do better if treated with angioplasty in high volume centers. Hospitals of low volume who would embark on such research would likely be in violation of PL 93-348, which requires hospitals to adequately protect the rights of human subjects recruited to participate in research. Second, a properly scripted informed consent would implicitly tell the patient that while this research is offered, there are better alternatives and courses of treatment in other settings. Informed consent must be written in a language the prospective subjects can understand…To do elective angioplasty research in Maryland hospitals, each consent form would need to clearly reflect that patients have less risk of death for the same procedure in an alternative, high volume setting….In closing, I urge the Commission to remove the recommendations allowing research exemptions for elective angioplasty on the basis it is unethical, and that a more systematic and scientific approach be developed if exemptions are to be allowed for primary angioplasty. I would also request the Commission to review the process of the registry for compliance with federal rules.

•**Peninsula Regional Medical Center** expressed concern about Policy 5.2. This policy provides for a pilot project to assess whether to allow hospitals without on-site cardiac surgery backup to perform elective angioplasty. Our view and that of the Technical Advisory Committee is that elective angioplasty should only be done in facilities with open heart backup. To do otherwise is clearly contrary to medical practice standards and patient safety. Current medical guidelines recommended by the American College of Cardiology and American Heart

Association state that elective angioplasty should only be performed in hospitals that operate open heart surgery programs. According to a recent study presented at the American Heart Association's Scientific Sessions 2000, "individuals undergoing non-emergency angioplasty in a facility that could not provide surgical backup were twice as likely to die, and 20 percent more likely to require bypass surgery for which they had to be transferred to another facility…. Unfortunately Dr. Wennberg's cautionary flag played itself out on the Eastern Shore. This past March a patient undergoing a diagnostic heart catheterization at a local Delmarva hospital suffered complications and needed to be transferred to Peninsula Regional for intervention. The patient did not survive and now the patient's husband is suing the referring hospitals for concealment of the facts, gross negligence, and deceptive trade practices.

•**Henry Meilman, M.D., Chief, Cardiac Catheterization Laboratory at Union Memorial Hospital,** wrote in opposition to expanding the exemption from the requirement that "elective" angioplasty programs be located in facilities with open heart surgery backup. He also expressed concerns about the continuation of the C-PORT program for the treatment of myocardial infarction with primary angioplasty….. There are many reasons why elective angioplasty should not be allowed at hospitals without surgical back up, even as a "research" project. There is a volume quality relationship with coronary angioplasty procedures. Numerous studies have shown and there is a consensus that patient outcomes are improved at centers performing at least 400 angioplasty procedures a year. There is additional improvement in centers performing 600 angioplasty procedures a year. Although rare, catastrophes requiring urgent surgical intervention still happen and are unpredictable. Patients requiring surgery are often more unstable than patients presenting with an acute myocardial infarction. Transferring such patients within an institution is often difficult. The idea of transferring them from one institution to another is unthinkable. It would probably be impossible to design an informed consent for such a project….Additional programs will be difficult to police and will have a negative impact on the volume of pre-existing programs. He also expressed concerns about the advisability of the C-PORT program. Recent data suggests that primary angioplasty is only superior to thrombolytic therapy at hospitals performing a high volume of interventional cases. The delivery of cardiac angioplasty services to patients with acute ischemic syndromes is a challenging and important aspect of the State Health Plan. He respectfully submitted that the best way to ensure equal access to modern high technology treatment of acute ischemic syndromes is to improve the inter-hospital transportation of patients.

•**Vanessa Aburn, Vice President of Cardiovascular Services at Union Memorial Hospital**, opposed the exemption for elective angioplasty programs. She indicated that MedStar in Baltimore had studied this issue in great detail……The small volume programs may never have the critical mass of patients necessary to achieve the high quality clinical outcomes and physician and patient satisfaction that the current providers have already demonstrated. She also noted that hospitals participating in an elective program may not be able to treat patients with angioplasty 24/7 and would likely choose to transfer patients "after hours" because of the difficulties in attaining staff and physician support. However, the American College of Cardiology strongly suggests picking one method of treatment in your facility and using it as the primary method of care. Having protocols that are in effect from 8 to 4 and others that are in effect after hours creates "gray areas" where delays become inherent. Cath lab staff must be hired, trained and continuously retrained. Elective programs will compete for the preciously few

trained staff, bidding up the salaries for all hospitals. Maintaining staff competency in a small volume program will be a challenge….Recently Union Memorial, Sinai, and St. Joseph's initiated a combined effort to work with Rural Metro to provide a critical care transport service. The effort is costly and laborious. The goals is to bring the patient to the best technology and the most highly trained, skilled staff in the most expeditious manner possible. Proliferating small volume programs will necessitate a critical care transport system that would be available to back up multiple hospitals for the emergency transports that will be necessary. Basically there will need to be nursing staffed, critical care transport units available at or close to elective angioplasty sites at all times. This is operationally and economically unfeasible.

•**Joseph Lindsay, Jr., M.D., Chief of Cardiology at Washington Hospital Center**, opposed the proposed regulations. The proposed regulations would allow primary or emergency angioplasty procedures to be performed at institutions that lack open heart surgery backup, without ensuring that operators are experienced in treating acute heart attack patients and without ensuring that laboratory teams are experienced in caring for these unstable patients. The proposed changes to elective angioplasty regulations would allow these non-urgent procedures to be performed in the absence of surgical backup, as well. This change in policy would expose otherwise non-critical patients to a small, but nonetheless real, risk of dying unnecessarily as a consequence of the procedure. It would also lead to a decrease in the number of procedures done in each laboratory, so opportunities for improved outcomes which are associated with increased experience would be lost….I understand that in your deliberations you must weight the rights of citizens to convenient access to even the most complex procedures against the fact that safer and more effective care is provided by experienced physicians, nurses, and technologists. In the case of angioplasty, both primary and elective procedures, quality care requires expert operators and the available resources to deal with complications.

Other Quality of Care Issues

•**Kathy Bradley, Coordinator of the Washington Adventist Hospital Cardiac Outreach Program**, opposed the proposed regulations……Treating cardiac patients involves more than a procedure. Treating cardiac patients must include prevention programs, diagnosis, a breadth of treatment options and rehabilitation. Only centers of excellence have the ability to ensure this full array of services. Many of the programs offered by Washington Adventist Hospital are free to the public, but we must underwrite the cost, and it is only through the volume of our cardiac surgery program that we are able to fund these types of programs. Redistributing cases from a Maryland program, which likely would occur if these regulations were approved, could potentially harm our ability to offer the breadth of prevention oriented programs that benefit the communities we serve.

•**William G. Robertson, President and CEO of Adventist HealthCare**, indicated that given the shortage of nurses and other key clinical staff, the proposed regulations will harm care at existing OHS providers in Maryland.

•**Peninsula Regional Medical Center** noted that in a tight labor market, new programs can damage existing programs and drive up salary levels. Specialized cardiac care services depend on highly specialized health care teams that include perfusionists, critical care nurses,

cath lab technicians, cath lab and OR nurses, and respiratory therapists. The labor shortages at area hospitals have been well documented, and Maryland hospitals are struggling to maintain the staffing levels required to operate. The reality is that new programs pose a real threat to maintain these teams. Competitive recruitment efforts will undoubtedly disrupt established teams as well as drive up salary level, adding further costs to the system. …The level of difficulty and the severity of heart disease of the patients they operate on is increasing. The reason for this is the increased use of these new interventional techniques and drug therapies. A portion of these patients will ultimately need surgery and when they do, they will be older and present a higher risk. The level of complexity these patients present demands an experienced hospital and an experienced operating team. The relationship between high quality surgical outcomes and volume are well documented and regulations that permit the expansion of open heart programs based on reasons other than demonstrated need is imprudent at best and deadly at worst.

•**Carol Woehlke, R.N., Director of Cardiology Services at Union Memorial Hospital**, wrote in opposition to the proposed regulations for the following reasons. First, to expand the elective angioplasty/intervention program to additional facilities would only stand to further dilute the already sparely populated pool of qualified and more importantly experienced critical care professionals…it took her a minimum of an additional three years of cath lab experience before she felt secure each morning on her drive to UMH that no matter what patient experience occurred in the lab, she would instinctively know how to handle it and to provide the patient with the best care.

•**Paul Corso, M.D., Director of the Cardiac Surgery Section of the Department of Surgery at Washington Hospital Center**, expressed concern that the proliferation of new programs and services will have a negative impact on existing institutions' abilities to attract, hire, retain, and train new staff to care for cardiac patients. Maryland is already experiencing a labor shortage in many of its specialized medical fields. A policy that supports proliferation in PTCA will aggravate the problem. Centers of Excellence provide services with staff who are often dedicated only to meeting the needs of cardiac patients. Diluting staff among more programs will impact programs' retention and patient ratios. It will extend the time needed for new staff orientation at every level of provider care.

C. Cost of Care Policies

Cost Effectiveness Standard

•**Jack C. Tranter, Esq., on behalf of Suburban Hospital,** indicated that if just 200 cardiac surgeries and 200 angioplasties were performed at either Suburban or Holy Cross Hospital instead of at the Hospital Center, savings to the Medicare program (and the American People) would be $4 million each year. These savings, as Drs. Atkinson and Cohen relate, result from the rate offers that an existing Maryland-based program must make in connection with the CON approval process. This phenomenon, and price reductions in response to the new, lower-priced competition, both generate savings to payers. This is precisely what occurred in the

Baltimore market as a result of the development of the two, new competitive programs at Sinai and Union Memorial during the last several years.

D. Access to Care Policies

Travel Time Standard

•**Angela J. Alvestad** wrote in support of the proposed State Health Plan and indicated that the citizens of Southern Maryland should be provided better access to OHS and angioplasty services. She stated that it is inconvenient for citizens of Calvert County to travel to D.C. or Baltimore for these services. There is also potential for delay in treatment if inclement weather would prevent air transport.

•**Martin L. Doordan, President of Anne Arundel Medical Center (AAMC)**, noted that many people suffer an acute cardiac episode, resulting in a trip to the emergency department. The plan recognized that immediate treatment is the best treatment. Heart muscle dies rapidly following a myocardial infarction. Prompt response, 90 minutes or less, leads to the best results…It does not matter to the patient that the best care in the entire world is available in a regional system if the patient is unable to get treated in time by the "regional system" that current CON laws have created. Delay can be fatal and is always debilitating…The issue is not that AAMC could not offer this level of care. In fact, AAMC offers care as sophisticated and "tertiary" every day…AAMC's more than 22,000 admissions make it one of the State's busiest hospitals—treating more than 7 of the 9 hospitals with cardiac surgery programs. Rationing open-heart and other sophisticated services may have been appropriate when community medical centers did not offer tertiary care but times and medicine have changed dramatically. The State Health Plan should reflect those changes. It does not because of its foundation in the concept of regionalized services. AAMC respectfully submits that the concept should be replaced with a patient-focused continuum of care approach.

•**Arthur P. Barletta, M.D., past President of the Medical Staff and Chairman of the Division of Medicine at Southern Maryland Hospital Center**, wrote in support of Southern Maryland Hospital Center for their request for cardiac surgical and therapeutic catheterization services. He indicated that there is a strong need for this service for the people of Southern Maryland. Many residents of Southern Maryland would rather have their care done in Southern Maryland as opposed to going to Washington, D.C. for a number of reasons to include: cost, transportation; lack of family involvement; and continuity of patient care with physicians who are currently taking care of these patients. He believes that there should be a choice for Southern Maryland residents to gain access to open heart and balloon angioplasty services other than the current Washington, D.C. programs…Lives can be saved, morbidity can be decreased and patient satisfaction can be increased when the services would be available on a more local process.

•**Laxmi N. Berwa, M.D., F.A.C.P.**, wrote in support of the proposed State Health Plan. He stated that there is a strong need for this service for the people of Southern Maryland. There is a need for better access to pen heart surgery and balloon angioplasty services for Southern Marylanders. Traveling into Washington, D.C. for these services is not convenient for the patients for family members.

•**Jean C. Blace, a Registered Nurse in the Clinical Care Unit of Southern Maryland Hospital Center**, wrote in support of the proposed State Health Plan. Due to population growth, she said that there is a strong need for these services in Southern Maryland. Transferring patients to services in Washington, D.C. is not convenient for patients or family members. If the weather is bad and MedStar cannot fly, urgent care is delayed, which can result in poor patient outcomes. There should be a choice for Southern Marylanders other than the current D.C. programs and Southern Maryland Hospital Center offers the perfect location for open heart and balloon angiography.

•**Barbara Brown** wrote in support of obtaining better access to specialized cardiac care services for the people of Southern Maryland. She said that she lives in Charles County and although she has not had to use these services personally, she is aware of others who have. The hardship and inconvenience of traveling to Washington, D.C. from Southern Maryland only adds to an already stressful situation. This could be alleviated if these services were available to the people of Southern Maryland.

•**Michele Chiriaco** wrote in support of the proposed State Health Plan. Seven years ago, her father-in-law had to have triple bypass surgery at Washington Adventist Hospital. It was difficult to coordinate getting my mother-in-law back and forth to the hospital to visit not to mention that we had to take by father-in-law to Washington Adventist for follow up care. She indicated that the people of Southern Maryland deserve to have these facilities closer to them…..This is a fast growing section of the State. We need this type of care available to us.

•**Talmadge L. Cooke** urged the Commission to support the proposed State Health Plan. As a citizen of Prince George's County, he felt it imperative for the residents of Southern Maryland to have quick and easy access to open heart and therapeutic catheterization services….It is very inconvenient for Southern Maryland residents to travel to Washington, D.C. or Baltimore for these services. Also, there is a potential for delay in treatment if inclement weather prevents air transport subsequently risking the health of the patient.

•**Debbie S. Ford, a resident of Charles County**, commented that there is a dire need for these services in the Southern Maryland area. This was even more clear to her after a friend ended up in the ED at Southern Maryland Hospital Center with chest pain…She was sent to Washington Hospital Center at which time she felt very scared and out of touch with her family and friends. She had real concerns and fears about leaving her young son with family and feeling so far removed….having a choice to stay in the area you live in versus going to DC is of great importance for the timeliness of care, comfort, and the healing process in these situations.

•**Peter P. Parvis, Esq., on behalf of Frederick Memorial Hospital**, noted the proposed chapter uses a two-hour travel time standard for 90 percent of the population for OHS. This

policy may still be appropriate for OHS services. Frederick Memorial Hospital questions its validity with respect to PTCA. In light of the critical importance of minimizing time between a heart attack patients coming to the emergency room and receiving care, this standard may need to be limited to OHS alone…Frederick Memorial Hospital believes that the Commission should explore difference standards for sole community hospitals to reflect their unique circumstances, at least with respect to PTCA….Access is woefully inadequate for Frederick County residents who come to their community hospital with chest pain. The plan stifles the development of appropriate cardiac care at sole community providers.

•**Mayzell Hawkins** wrote in support of the establishment of a cardiac surgery and therapeutic catheterization service at Southern Maryland Hospital Center. Having these services at Southern Maryland Hospital is critical to providing appropriate full services to the people of Southern Maryland. As of right now, cardiac patients must travel to Washington, D.C. or Baltimore for these services. This puts unnecessary hardships on patients and their families.

•**Heather L. Henley** wrote in support of the proposed plan and noted that the regulations are consistent with the strategy of managed growth in the number of cardiac surgery programs. The regulations will improve quality and access at an affordable price. She supported Suburban Hospital's intent to compete for a CON for cardiac surgery under the proposed regulations. It is her understanding that a cardiac surgical program led by surgeons who are members of the Johns Hopkins School of Medicine faculty with appointments at the National Heart, Lung, and Blood Institute and based at Suburban Hospital will be a welcome alternative for patients who now travel away from our community for surgery or elective angioplasty.

•**Gurbux H. Nachnani, M.D., F.A.C.P., F.A.C.C.,** who has practiced cardiovascular diseases in the Southern Maryland area for the last 30 years, said that since there is no cardiac program in the Southern Maryland area, that they have no choice but to refer patients to the Washington Hospital Center and George Washington University Hospital. The Heart Center of Southern Maryland refers close to 1,000 patients for invasive and interventional cardiac studies to the Washington Hospital Center…over 100 patients undergo coronary heart bypass at Washington Hospital Center. Most of these patients are elderly patients. It is sad to see that families and patients have to travel all the way to Washington, D.C. to obtain this care that could be easily provided in our area. I strongly feel that Southern Maryland Hospital Center should have an open hart surgical program. Citizens of Southern Maryland deserve to have this program made available to them in this area so that they do not have to face traffic and other inconveniences associated in traveling to the District of Columbia. We do perform cardiac catheterizations at Southern Maryland Hospital Center, however, we cannot perform angioplasties and deploy stents in coronary arteries unless there is a standby open heart surgical program.

•**Susan L. Lord, of Waldorf, Maryland,** urged the Commission to support the proposed State Health Plan. She said that her 57-year old mother required transport to the Washington Hospital Center and subsequently had triple by-pass surgery. Her mother survived the surgery and is recovering. However, as a citizen of Charles County, she believes that it is very inconvenient for people to travel to Washington, D.C. or Baltimore for those services. Also, there is a potential for delay in treatment if inclement weather would prevent air transport,

fortunately for my mother the weather was suitable that day for air travel and may very well saved her life. I believe that all citizens of the Southern Maryland area should have closer geographic access and choice for open heart and therapeutic catheterization services.

•**Sandy MacLean, R.N.,** a resident of Prince George's County, wrote in support of the proposed State Health Plan specifically endorsing the expansion of current cardiac surgical and catheterization services…I feel strongly that these services would greatly benefit the residents of Southern Maryland. As a critical care nurse, she indicated that she routinely encounters patients who must be transported to other hospitals in order to receive therapeutic catheterization and cardiac surgical services. At best, the relocation is inconvenient and worrisome for patients and families. At worst, it substantially delays definitive treatment and places the patient at increased risk for further compromise. …I also have the experience as a "family member" of a cardiac surgical patient. My mother was diagnosed as having triple vessel disease and aortic stenosis, both of which would require open heart surgery. We began our trips to the Washington Hospital Center February 11, 2000. First, there was the cardiac cath, then the meeting with the surgeon, then the pre-op workup, then the surgery and an extended post-operative recovery period. On April 12 she was discharged from the hospital to return home. Travel to and from Washington, D.C. nearly everyday for seven weeks was inconvenient, exhausting, and even scary at times….One year later mom is doing great, but to this day she still asks me, "Why don't you do that surgery at your hospital?" I never have a good answer.

•**Sharon A. Main**, a long time resident of Southern Maryland, wrote in support of the expansion of cardiac surgery and balloon angioplasty services in the Washington Metropolitan area and more specifically in Southern Maryland. As family, friends, and I age, I recognize that full cardiac care may be required for someone I love. It takes a minimum of 90 minutes to reach a facility which offers open heart and balloon angioplasty—that is with the best of traffic and weather conditions. ..As a long time resident of Southern Maryland, I have witnessed the rapid growth and development in this region. Although this development has contributed to the prosperity of the region, in my opinion, there has been little consideration given to the expansion of healthcare service. Our local community hospitals have adapted to our needs to the extent allowed to them by regulations and law. As we look ahead, we can only project that more people will opt to live in Southern Maryland and we must ensure that adequate access to cardiac services in a location outside the beltway. The population of this region is aging and the need for additional services is growing….In closing, I only hope that the decision-makers for these critically needed healthcare services will not be unduly influenced by the inner beltway healthcare systems…

•**Richard G. McAlee, Esq., on behalf of Southern Maryland Hospital Center**, wrote in support of the approval of the open heart surgery chapter as a final regulation. He also commended the Commission and its staff for proposing a fair and reasonable solution to the competing concerns about access and quality of care. There are compelling arguments in favor of better geographical access for Maryland residents to cardiac surgery and angioplasty. The cardiology maxim that "time is muscle" succinctly summarizes the critical importance of ensuring that a full range of interventional cardiac services be available to all Maryland residents within their immediate geographic area. Travel times alone seriously understate the delays that inevitably occur when a patient undergoing cardiac arrest arrives at one hospital, undergoes

triage, and then must be transferred to another hospital with the ability to provide cardiac services needed by that patient. On the other hand, there are legitimate quality of care concerns about spreading cardiac surgery services among too many hospitals. Not every hospital is prepared to provide cardiac surgery, and spreading the caseload over too many programs would result in some programs without the requisite "critical mass" of cases to ensure a high-quality program. The position proposed by the Commission entails a balancing of these concerns and a conservative solution: expand the number of cardiac surgery programs by only one program at this time, and only in the Metropolitan Washington area. A new program in that area-especially if is located in a relatively underserved portion of the area—would have no adverse impact on existing providers, and would allow all programs the ability to achieve and maintain the necessary volume of cases.

•**Susan McNeill-Smith**, a critical care nurse who has worked at a small community hospital in the Southern Maryland area for ten years, noted the importance of expedient care to maximize the overall health care benefits to patients. She stated her support for the proposed State Health Plan and indicated that many patients and families enjoy coming to an area hospital in their community. They would prefer not to be transferred to a metropolitan D.C. hospital for further evaluation and treatment of their cardiac disease. It is a hardship for patients and their families to travel over an hour for their follow-up care. Southern Marylanders should have the right to choose where they their balloon angioplasty services and open heart surgery performed.

•**Julie Ann Murphy**, a mother of three and a resident of Charles County, wrote in support of the proposed plan as published in the January 26, 2001 Maryland Register. Knowing that these essential services are not provided at any of the local hospitals is concerning. For these services affecting the heart, having closer access is imperative for improving the health for the people of Maryland.

•**Richard A. Stout, President of Protectogon, Incorporated**, wrote stating support for Suburban Hospital should it decide to complete for the awarding of a cardiac surgery unit under the proposed regulations. He suffered a heart attack approximately nine years ago and was successfully treated at Suburban Hospital with clot-busters. He was very well cared for by the Suburban Hospital staff and would highly recommend this institution as a new cardiac surgery facility, particularly if the program is led by surgeons who are members of the Johns Hopkins School of Medicine faculty. Such a facility would provide a very attractive alternative for patients who must now travel considerable distances for surgery or elective angioplasty.

•**Audrey S. Sledd** wrote in support of the proposed State Health Plan and said that the residents of Southern Maryland need a choice when it comes to cardiac care. She noted that time is of the essence when it comes to cardiac care. All the current programs are inside the beltway and in Baltimore. Those places are just too far. We need to have direct access in Southern Maryland for the residents of lower Prince George's County, Charles County, Calvert County and St. Mary's County.

•**Ralph W. Torr, M.D., Chief, Division of Anesthesiology at Southern Maryland Hospital Center**, wrote in support of the new proposed State Health Plan related to cardiac

surgery and balloon angioplasty…the new plan would provide better access to the many residents who now must travel into Washington, D.C. for this service.

•**William M. Spruce, Jr.** wrote in support of Southern Maryland Hospital Center obtaining the authority to perform heart surgery and other cardiac care at this location. He stated his belief that this approval would provide the citizens of Southern Maryland with a much needed service. Even though he received outstanding care at the Washington Hospital Center, its location was very inconvenient for my family and friends…Having a facility providing complete cardiac services in Southern Maryland would contribute to improving care and response time for cardiac patients. Stress would be reduced for families supporting cardiac patients by reducing the time spent during inclement weather and distance that must be traveled.

•**Gary Staples, M.D.**, on behalf of a group of radiologists serving the southern Maryland area, wrote in support of the new state health plan regarding specialized cardiac surgery and therapeutic catheterization services. In our role, we are aware of the many patients in this area who have to be transported into Washington, D.C. for these procedures. This is often a time consuming process, and we feel better access for these services is needed. Allowing one new program in the Washington, D.C. region is imperative, and therefore, we urge the Commission to approve the plan as proposed.

•**Cardiology and Internal Medicine, P.D. (Drs. Joseph A. Romeo, Harris A. Kenner, Joseph A. Vassallo, Bruce S. Talesnick, Lewis C. Lipson, Sean M. Dwyer) and Cardiac Consultants Chartered Drs. Thomas G. Sinderson, Roger Stevenson, Jr., Harry J. Bigham, Jr., Yuri A. Deychak, Samuel Dr. Goldberg, Douglas R. Rosing, Mark R. Milner, and Virignia C. Colliver)** supported the findings that a new cardiac surgical program is needed in the Washington, D.C. Metropolitan Area. In contrast to the well balanced Baltimore market with five evenly balanced programs, each doing more than 400 cases a year, the Washington market is comprised of a very large program at the Washington Hospital Center and a much smaller program at the Washington Adventist Hospital. …We believe that a new program in suburban Maryland will provide easier access and choice for our patients, and we could encourage out patients to use the new program, particularly if Suburban Hospital were chosen to provide this service. In addition, as you well know, elective PTCA cannot be done in a hospital without a cardiac surgical program, The establishment of a new program would be most helpful to patients who need elective angioplasty as well as bypass surgery.

•**Virgil Hood, Sr.** wrote in support of the proposed regulations and indicated that he believed these regulations are consistent with a strategy of managed growth in the number of cardiac surgery programs. As a senior citizen, he looks forward to improved quality of care and access at an affordable price resulting from these regulations. Moreover, he enthusiastically supported Suburban Hospital's intent to compete for a CON for cardiac surgery under the new proposed regulations.

•**Martin Strauss**, who is currently in a cardiac rehabilitation program at Suburban Hospital, said that it would be very advantageous and provide ease of mind if Suburban Hospital could provide cardiac surgery, especially when led by Johns Hopkins surgeons.

•**Lewis F. Morse** indicated that residents of Montgomery County need improved access to first class cardiac services. For this reason, he supported Suburban Hospital's efforts to obtain a CON to perform angioplasty procedures and cardiac surgery.

•**Joseph F. King** wrote in support of the regulations and stated his belief that they are consistent with the strategy of managed growth in the number of cardiac surgery programs. The regulations will improve quality and access at an affordable price. He supported Suburban Hospital's intent to compete for cardiac surgery under the new proposed regulations.

•**Leon J. Niemkiec, Ph.D.,** wrote in support of the regulations and stated his belief that they are consistent with the strategy of managed growth, improvement of quality and access at an affordable price. Suburban Hospital as a community non-profit institution is an invaluable resource. A cardiac surgery program would not only meet an urgent local need, but also provide vital cardiac emergency services to the growing Washington, D.C. regional area.

•**David L. Lowery,** wrote in support of the regulations and stated his belief that they are consistent with the strategy of managed growth, improvement of quality and access at an affordable price. He supported Suburban Hospital's intent to compete for a CON for a cardiac surgery program.

•**Allen Anderson** wrote in support of the regulations and stated his belief that they are consistent with the strategy of managed growth, improvement of quality and access at an affordable price. He said Suburban Hospital is a superb hospital. A cardiac surgical program based at Suburban Hospital will be a welcome alternative for patients who now must travel away for surgery or for elective angioplasty.

•**Melvin W. Wachs** noted a need for an additional cardiac surgery program in the Washington, D.C. area based on a managed growth strategy. He strongly supported certification of Suburban Hospital in this area. The Suburban program should prove to be a much needed and desirable alternative for servicing the needs of patients who now must travel far from Suburban Hospital's geographic area for surgery or elective angioplasty.

•**Carl Goldberg** wrote that there is a definite need for this protocol to be offered in this part of Montgomery County as the Hospital Center and Adventist Hospital are very inconvenient to reach from Western Montgomery County.

•**Norbert Halloran** wrote in support of Suburban Hospital's application for approval of a cardiac surgery program. He said that it would have been a comfort and convenience if he could have received heart surgery at Suburban Hospital, in the same hospital he is now doing the follow-up exercise. It makes a lot of sense if southern Montgomery County's population center of Bethesda can have available in one facility (Suburban Hospital) all major cardiac treatment programs.

•**Manuel Vera** wrote in support of the proposed regulations on cardiac surgery. He indicated these regulations are consistent with a sound strategy of managed growth in the number of cardiac surgery programs, and that the regulations will improve quality and access to cardiac

surgery facilities at an affordable price. He also supported Suburban Hospital's intent to compete for a CON for cardiac surgery under the new proposed regulations.

•**Claude Lefant, M.D., Director of the National Heart, Lung, and Blood Institute at NIH,** indicated that NHLBI plans to reestablish a research effort in cardiac surgery and noted that NHLBI and the National Institute of Neurologic Diseases and Stroke have ongoing, successful research collaborations with Suburban to assess the use of MRI in patients with suspected heart diseases, and the diagnosis and treatment of patients who have had an acute stroke. He said that if Suburban is able to obtain a CON to provide cardiac surgery that he believed that a joint cardiac surgery program between NHLBI and Suburban could be developed. He supported the proposed regulations allowing the development of a new cardiac surgery program in the Washington Metropolitan area. If an opportunity exists for the development of a new open heart program in the Maryland suburbs of Washington, D.C., the NHLBI will join with Suburban and vigorously compete for Commission approval.

•**Audrey M. Weston** wrote in support of the proposed State Health Plan. The people of Southern Maryland deserve to have the service of open heart surgery and balloon angioplasty available to them. If Southern Maryland Hospital Center could offer these procedures to Southern Marylanders, it would be more convenient for the patient and their family members. The people who live in Southern Maryland should have a choice of where to have these procedures performed.

E. Other Policies

Eligibility to Meet New Need

•**Warren A. Green, President and CEO of LifeBridge Health**, noted that under the proposed regulations, should demand for open heart surgery grow to a point where it exceeds available capacity, only providers without existing programs may apply for the right to meet that additional demand. We simply do not understand the justification for denying existing providers the right to complete to meet the additional demand, particularly in Central Maryland where geographic access is not an issue. Surely it is possible that the most economically and clinically sound method of meeting incremental demand will be to expand the capacity of one or more existing providers, rather than starting a new program entirely from scratch. By eliminating the option of meeting incremental need through expansion of existing resources, the proposed regulations unwisely limit the Commission's ability to plan a rational and efficient health care delivery system.

Number of New Programs Allowed

•**Wynee E. Hawk, Vice President for Government Relations at GBMC**, commented that access should not be held to a one hospital at a time approach, which really means a one or two hospitals a decade.

•**Raymond A. Grahe, Vice President for Finance at Washington County Hospital,** wrote in opposition to a limitation on the number of new programs allowed in a specific region by the Commission. If in fact the volume and need is demonstrated within a particular region to support two programs above minimal capacity standards that are established by the Commission, when such program should be allowed to be developed. (John H. Hornbaker, Jr., M.D., Gary Papuchis, M.D., Jeffrey D. Jones, M.D., Zubair H. Faridi, M.D., Scott M. Hamilton, M.D., and W. Stephen Hood, M.D. wrote to endorse and support comments from the Washington County Hospital.)

Other Policy Issues

•**William G. Robertson, President and CEO of Adventist HealthCare,** indicated that the proposed regulations do not reflect sound health planning in compliance with the applicable requirements of the CON laws. We believe that the question put before the Commission, particular in the Washington Region, is whether there are enough OHS programs in meet future needs, and not whether additional hospitals should be given the opportunity to compete for a CON to offer OHS services….It is evident from the Commission's own data that there are enough OHS programs in the Washington Region to meet all of the community's needs, both for the present and through the Commission's projected target year, 2002. The growth in the number of forecasted OHS cases is minimal, there are accessible OHS programs throughout the region, there are no waiting times, and every Marylander in the Washington Region who might choose to receive OHS in a Maryland hospital in the region can be readily accommodated in existing programs. The proposed regulations propose a radical departure from the historical approach to planning for this specialized, regional service, in a manner that is unsupported by data, research, and the advice of the Commission's own TAC of experts from all manner of hospitals. In so doing, the Commission has proposed regulations that are inconsistent with the Commission's health planning law and otherwise applicable constitutional law.